| Elaboration: Karine Lima | Review: Ana Luiza Duz | Approval: Cláudia Azevedo | Implementation Date:

October 28, 2022 |
|---|---|---|---|

I.   REASON FOR REVIEW

Review	Historic	Approval Date
09	Review of the specifications of packaging materials in compliance with the actions by the selected materials Gap Analysis GA01/2021, 14/2021, 15/2021, 19/2021, 09/2022 and 34/2022 and by the Change Controls CM 17/2021, 18/2021, 25/2021, 02/2022 and 05/2022. According to the proposed amendments ID 11/2022. There is no training that requires an implementation of the document in the QMS.	October 24, 2022
00	Initial issue.	January 8, 2019

GOAL

Provide the specifications of the packaging and labeling used in the models of the Keraring Intrastromal Corneal Ring product (SI5, SI6, SG, AS5 and AS6) under the scope of the CE marking.

II.   SCOPE

This document applies to the Production (Implant Quality and Cleaning - QLI and Packaging), Supply, Logistics and Quality Management and Regulatory Affairs sectors.

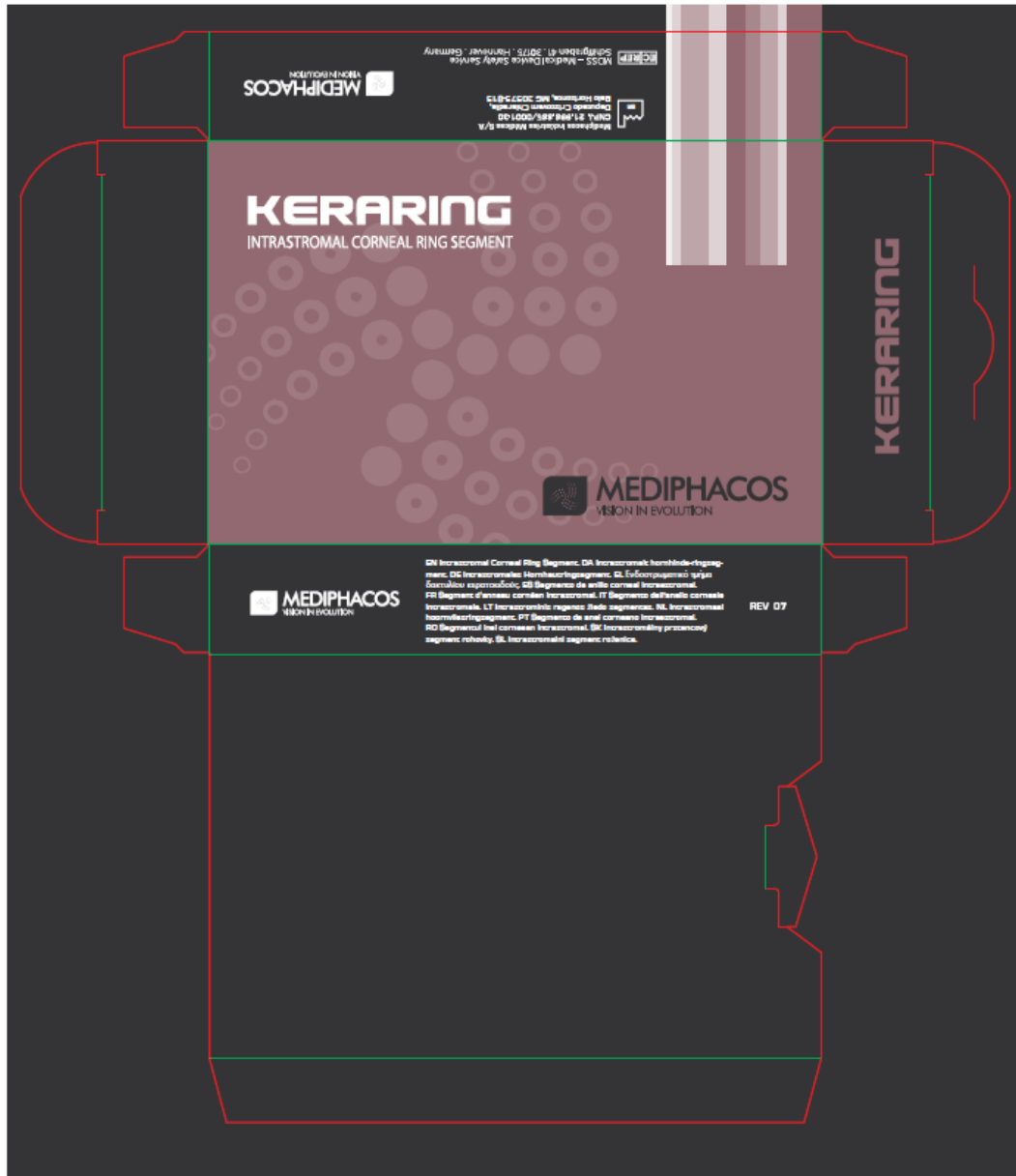## III.   TECHNICAL SPECIFICATIONS

4.1. Models and Specifications

4.1.1 Primary packaging

See current version DET IC 14.

4.1.2. Secondary packaging

See current version DET IC 30.
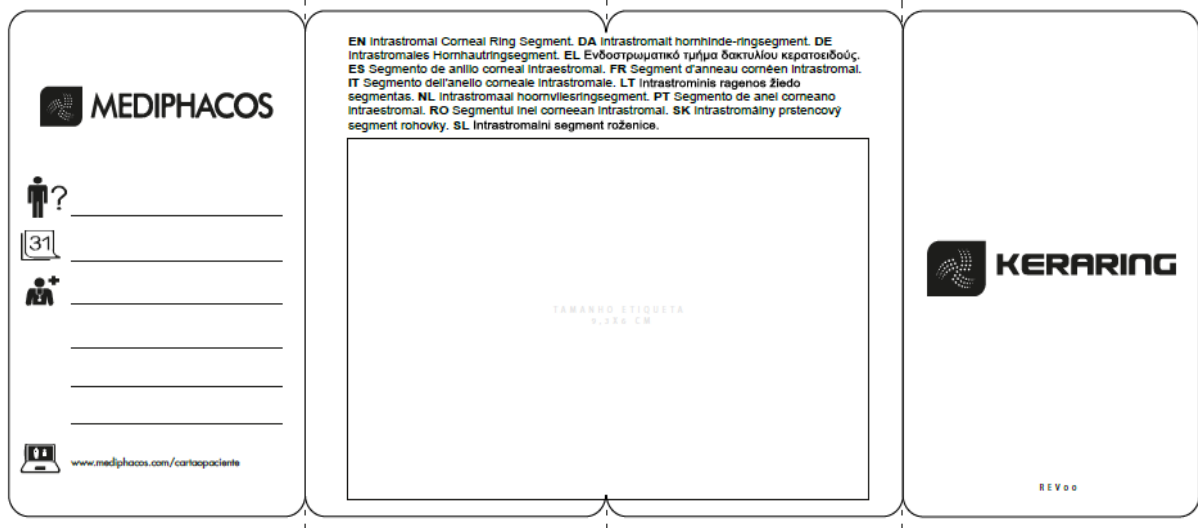
4.1.3 Tertiary packaging:

- **Layout:** 200020004 Keraring Cardridge Rev 07
- **Dimensions (close):** 96 x 26 x 145 mm
- **Dimensions (open):** 25,5 x 24,0 cm
- **Material:** black ink in lamination and gloss on side 1
- **Grammage:** 325 g
- **Collors:** 3 x 0
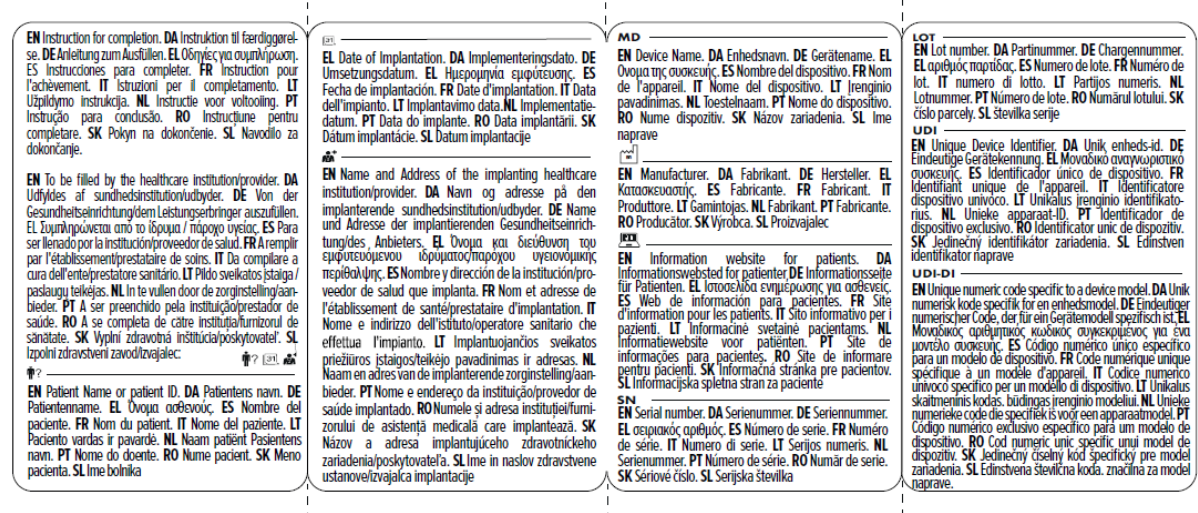- **Pantones:** 8062 C, 7633 C and Black C
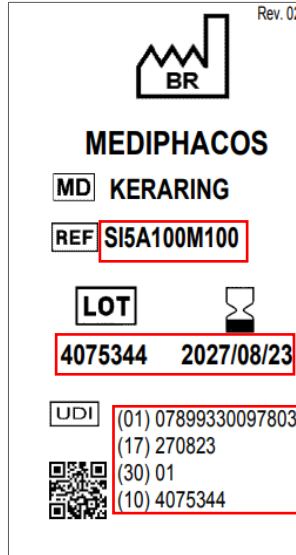
4.1.4 Implant card:

FRONT

VERSE

- **Layout:** 200050081 Keraring Implant Card Rev00
- **Dimensions:** 320 x 95 mm
- **Material:** black ink on vitabianco card, gloss lamination
- **Weight:** 325 g (printed double-sided with creases for 03 folds)
- **Pantone:** Black C
- **Disposition**: inserted inside the tertiary packaging (cartridge)
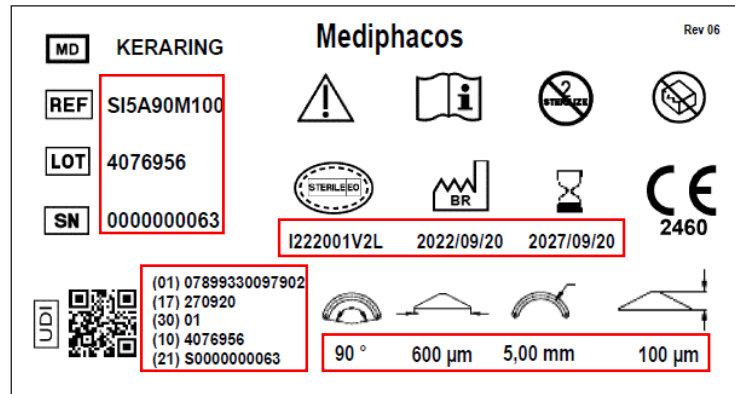
4.1.5 Labels
4.1.5.1 Primay packaging label

Variable data: reference, lot (OP), expiration date and UDI

- **Layout:** 200050026 Universal Case Label Rev 02
- **Dimensions:** 44 x 22 mm
- **Material:** couchê borracha
- **Disposition:** affixed in the primary packaging (case) of the product.
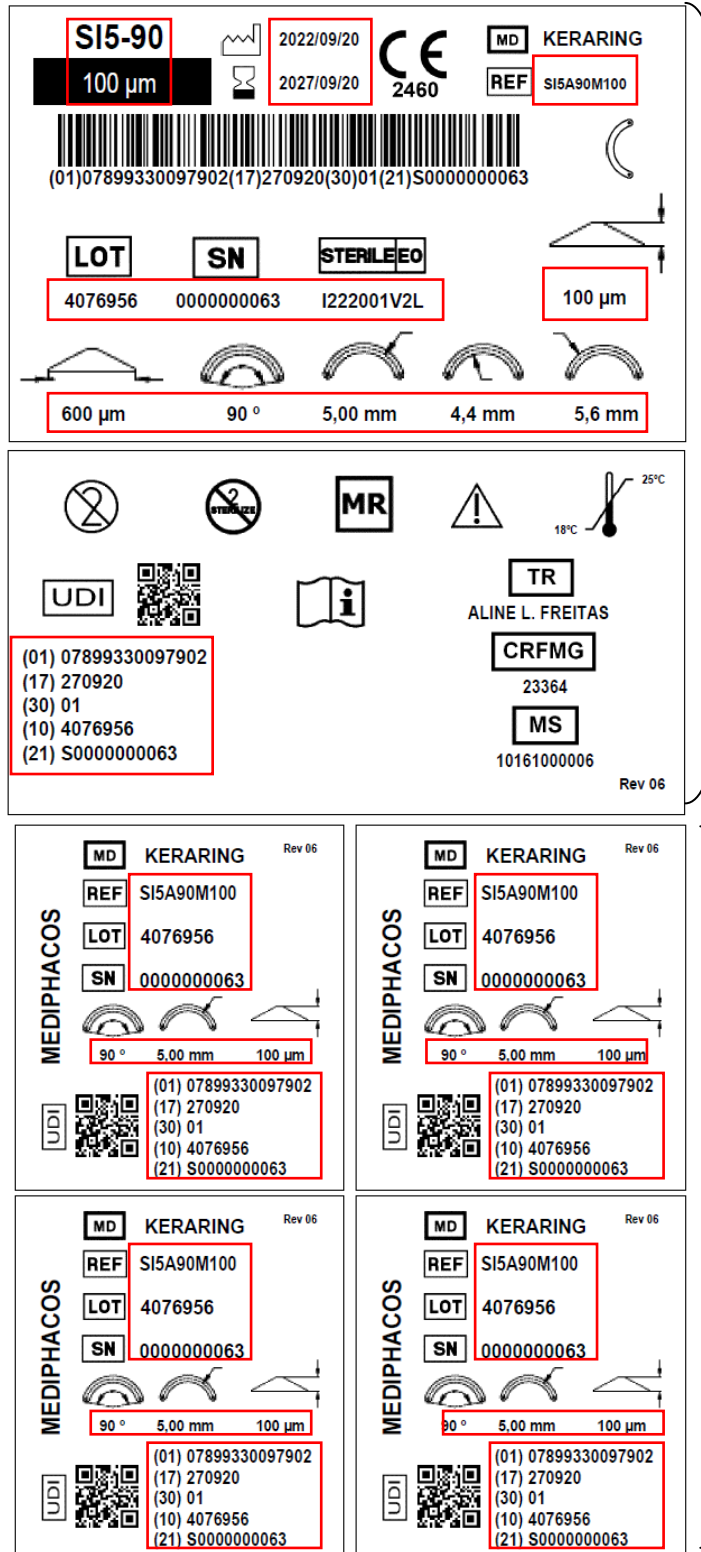
4.1.5.2 Secondary packaging label

Variable data: reference, lot (OP), serial number, sterilization lot, date of manufacture, expiration date, UDI and model specifications.

- **Layout**: 200050003 Zebra Autofit Tag Rev 06
- **Dimensions:** 97 x 220 mm
- **Material:** resin adhesive, transthermic
- **Front material:** 67 to 75 ; 71 micron
- **Protective material:** 52 to 59; 55.5 g/m2
- **Total weight:** 133 to 150; 141.5 g/m2
- **Total thickness:** 132 to 150; 141 micron
- **Release:** 6 to 14; 180º gf/1in
- **Type of printing:** flexography
- **Varnish:** no
- **Minimum spacing:** 3mm ±1

- **Disposition:** affixed in the secondary packaging (envelope) of the product.

4.1.5.3 Tertiary packaging labels:

a) **Symmetric models: SI5 and SI6**

Labels affixed to tertiaty packaging (cartridge)

Labels inserted inside the tertiary packaging cartridge

Variable data: reference, lot (OP), serial number, sterilization lot, date of manufacture, expiration date, UDI and model specifications.

b) **Asymmetric models: ASI5 and ASI6**

Labels affixed to tertiaty packaging (cartridge)

Labels inserted inside the tertiary packaging cartridge

Variable data: reference, lot (OP), serial number, sterilization lot, date of manufacture, expiration date, UDI and model specifications.

c)   **SG Models**

Labels affixed to tertiaty packaging (cartridge)

Labels inserted inside the tertiary packaging cartridge

Variable data: reference, lot (OP), serial number, sterilization lot, date of manufacture, expiration date, UDI and model specifications.

- **Layouts**:
  200050003 Zebra Autofit Tag SI Rev 06
  200050003 Zebra Autofit Tag AS Rev 06
  200050003 Zebra Autofit Tag SG Rev 06
- **Dimensions:** 97 x 220 mm
- **Material:** resin adhesive, transthermic
- **Front material:** 67 to 75 ; 71 micron
- **Protective material:** 52 to 59; 55.5 g/m2
- **Total weight:** 133 to 150; 141.5 g/m2
- **Total thickness:** 132 to 150; 141 micron
- **Release:** 6 to 14; 180º gf/1in
- **Type of printing:** flexography
- **Varnish:** no
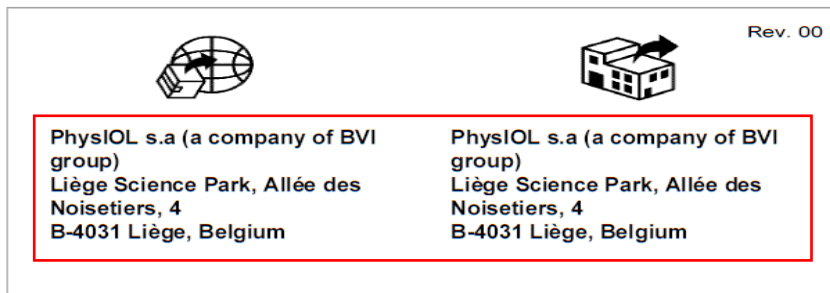- **Minimum spacing:** 3mm ±1

4.1.5.4 Implant card label:
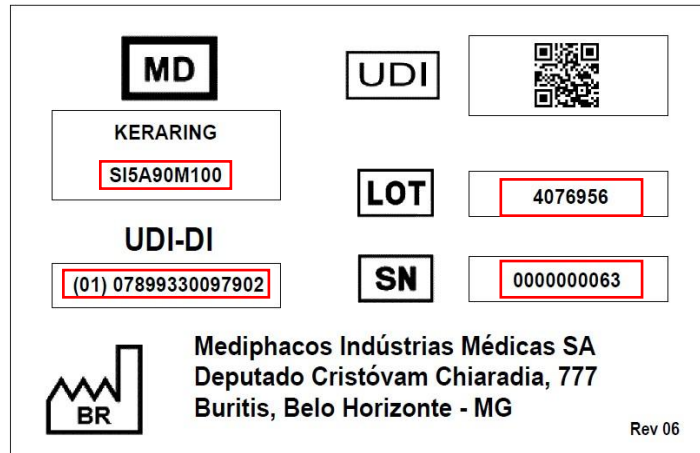
Variable data: reference, lot (OP), UDI-DI and serial number

- **Layout:** 200050003 Sticker Zebra Autofit Implant Card Rev 06
- **Dimensions:** 9,3 x 6,0 mm
- **Material:** resin adhesive, transthermic
- **Disposition:** affixed to the implant card.

4.1.5.5 Importer and distributor label

Variable data: name and address of the importer and distributor.

- **Layout:** 200050085 Keraring Importer and Distributor Label Rev 00
- **Dimensions**: 80 x 40 mm
- **Material:** rubber couch
- **Disposition:** affixed by the European Community importer to the tertiary packaging (cartridge).

Note 1: If there is any need to change the layout or the information on the label 200050085, the Mediphacos logistics sector, the Mediphacos importer in the European Union and the other importers to which this label applies must be communicated.

4.1.5.6 Shipping label

Variable data: ID code, name, customer address, shipment ID and barcode.

- **Layout:** 900060042 Shipping label
- **Dimensions:** 105 x 138 mm
- **Material:** Coated Paper
- **Adhesive:** Acrylic
- **Arrangement:** Affixed to the product's transport boxes.

4.1.1 Primary packaging security seal
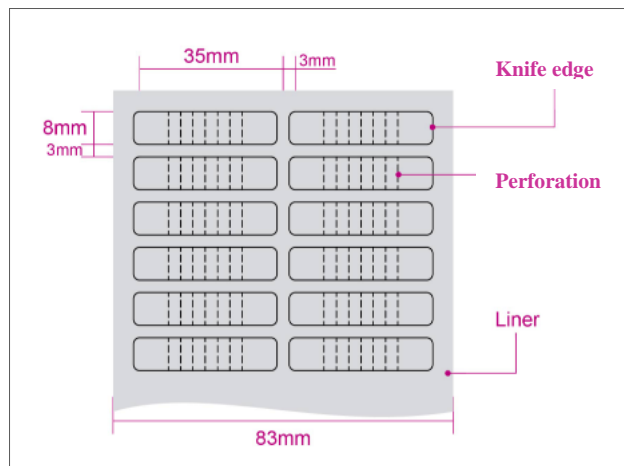
- **Layout:** 200030059 Security Seal Labels for Cases Rev 00
- **Dimensions**: 35,0 x 8,0 mm
- **Material:** bopp transparent, adhesive acrylic
- **Disposition:** affixed to the cover and body of the primary package (case).

4.1.6 Embalagem de embarque

See current version EE EMB 17.

4.1.7 Instruction for use:

- **Layout:** 200010006 IFU Keraring Rev 11
- **Disposition:** inserted in the tertiary package (cartridge).

IV.   ANNEXES

Not applicable.

V.   REFERENCES

ANVISA. Resolution of the Collegiate Board - RDC N 665, of March 30, 2022.

MDR EN ISO 13485:2016_A11:2021 - Medical devices - Quality management systems -Requirements for regulatory purposes.

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

EN 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements.
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

EN ISO 20417 2021&LC:2021- Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12).

IPA GQA 08 - Packaging and Marketing Material Control

DET IC 14 - Keraring Case

DET IC 30 Tyvek Surgical Grade Paper Envelope EO 8x18

EE EMB 17 Shipping Boxes